There have been very few studies of treatment refusal generally, or, more specifically, of the effects of risk disclosure on subsequent treatment decisions. Anecdotal reports document that at least some patients refuse treatment because of fear of the therapy. However, in one of the Commission's observational studies, which was the first systematic attempt to determine the frequency of treatment refusals and their causes and outcomes, refusals were found to occur about once per 15-20 patient days. As indicated earlier in this Chapter, most involved minor treatments, not life-threatening procedures. And, perhaps most importantly, the trigger for refusing treatment was not too much but too little information. Patients who refused treatments typically did so because the nature, purpose, and attendant risks of the procedures had not been adequately explained.

The Relationship of Ethical and Legal Standards

From all that has been said, it is clear that the disclosure and communication processes should be geared to the needs of particular patients in given health situations. Professionals should seek to elicit the individual's goals and values and to frame the discussion in those terms, with due regard to the patient's emotional needs and intellectual capacities. To what extent can or should the law aid movement in this direction?

The Development of Legal Rules. To date, no American jurisdiction has adopted legal requirements for informed consent fully congruent with the ethical objectives set forth in this Report.[60] The reasons for this are partly historical: in most jurisdictions, failure to obtain informed consent is treated as a form of medical negligence or malpractice. To assess whether a particular act or omission constitutes malpractice, the legal system usually relies on professional standards of practice. Thus, in a lawsuit alleging lack of informed consent, the behavior of the defendant has traditionally been assessed in light of the "professional standard" of disclosure—that is, what other physicians would have disclosed in like circumstances.

The law's treatment of informed consent claims as a kind of medical negligence and the resulting adoption of the professional standard of disclosure tacitly assume that full disclosure is a recognized part of accepted medical practice, and that departures from it label the practitioner as failing to live up to the professional standard. This assumption has been extensively criticized by scholars.[61] Although both disclosure

60 *See generally* Katz, *supra* note 1.

61 *See, e.g.*, Capron, *supra* note 36, at 407-10; Katz, *supra* note 1, at 154-60.

and consent have long been advocated and practiced by some,[62] medical practice did not join the dual obligations of disclosure and consent in the sense of "informing for decision" until very recently. Thus reliance on a professional standard of disclosure is unlikely to provide much legal encouragement for the ideal of effective patient participation in decisionmaking set forth in this Report. Nevertheless, to the degree that professional attitudes and standards change over time in the direction of greater respect for, and encouragement of, patient participation in decisionmaking, the use of a professional standard will conform more closely with the objectives set forth in this Report.

Since 1970, a number of American jurisdictions have abandoned use of the professional standard and moved at least part of the way toward a legal standard oriented more to the needs of the particular patient. With some variation in specifics, these courts have stressed that the standard of disclosure is properly set by society rather than by the medical profession, and they have adopted a standard that responds to the informational needs of the hypothetical "reasonable patient."

The Commission finds this approach commendable in recognizing that the appropriate standard is societal rather than professional and in redirecting the inquiry toward the needs of the patient. However, a standard based only on the needs of a reasonable patient offers no assurance that either the well-being or the self-determination of a particular patient will be advanced by the workings of the law.

Numerous commentators have urged that the law of informed consent take the next step, moving beyond the reasonable patient standard to one that is more attentive to the informational needs of particular patients.[63] The critical issue in this debate concerns the degree to which providers should be legally required to take into account the informational needs of particular patients that differ from those of the "reasonable patient." Some commentators focus on apparent differences; others call upon practitioners to press their patients for a clearer articulation of their individual goals, values, and informational needs, which would then set an individual standard for disclosure. Such an evolution in legal requirements would move the law into closer conformity with the moral obligations of health care professionals that are set forth in this Report.

62 Martin S. Pernick, *The Patient's Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy* (1981), Appendix E, in Volume Three of this Report.

63 *See* note 61 *supra.*

64 There are some informed consent cases and statutes that can be read as suggesting a more individualized or subjective approach

No jurisdiction has yet clearly taken this step.[64] Indeed, in a number of states where courts have adopted the reasonable patient standard, legislatures have reimposed the professional standard by statute.[65] Their hesitancy to bring legal standards into closer conformity with moral obligations is in part practical and in part political.

Much of the difficulty arises from the fact that moral obligations define a standard of conduct for individuals while legal requirements must also be enforceable. Enforcement typically occurs via litigation conducted long after injuries have occurred, on the basis of evidence that may include selective and self-serving assertions by parties with a considerable stake in the outcome. Such a situation makes reliable determinations of the individual parties' wishes, needs, and intentions regarding the original communication very difficult, which helps explain the law's decided preference for more objective standards, even at the cost of some injustice in particular cases.[66] Thus there must be some balance between the ethical objectives the law seeks to encourage and the technical demands of a workable litigation process. The Commission recognizes that further evolution of legal standards toward a firmer protection of individual self-determination in medical decisions must be tempered by a recognition of the law's limits as an instrument of social control.[67]

Attitudes toward the Law. In the Commission's survey, several questions to physicians and the public dealt with the legal doctrine of informed consent. The majority of both groups agreed that patients' rights to information should be protected by law (see Figure 3). However, significantly more physicians than patients agreed with the statement "Time spent discussing diagnosis, prognosis, and treatment could be better spent taking care of patients." The public was more likely than physicians to think that the legal requirements for obtaining

---

toward determining what must be disclosed to patients, though no court has ever expressly held that a health care professional must disclose what the particular patient would have wanted to know. A similar issue exists with respect to the test of causation to be employed. Although courts have not only hinted but actually decided that whether or not the failure to disclose "caused" the patient's injury is to be determined by reference to whether or not a "reasonable" person would have refused the treatment had he or she been properly informed, a few cases and statutes have begun to reject this formulation, focusing instead on whether the particular patient would have refused treatment had disclosure been proper.

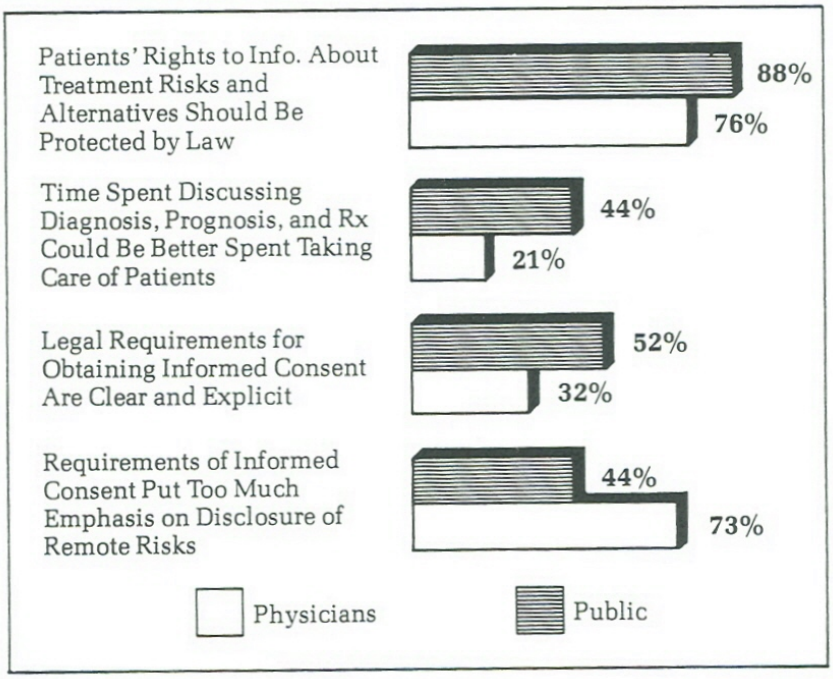
65 *See* Alan Meisel and Lisa D. Kabnick, *Informed Consent to Medical Treatment, An Analysis of Recent Legislation*, 41 U. PITT. L. REV. 407, 423-26 (1980).

66 Canterbury v. Spence, 464 F.2d 772, 790-91 (D.C.Cir. 1972).

67 See Chapter Seven *infra* for a further discussion of possible legal developments.

Figure 3: The Legal Doctrine of Informed Consent: Public and Physician Views

Source: Commission survey conducted by Louis Harris and Associates, 1982



informed consent were clear and explicit (52% versus 32%), and doctors were more likely than the public to feel that the requirements put too much emphasis on disclosure of remote risks (73% versus 44%).

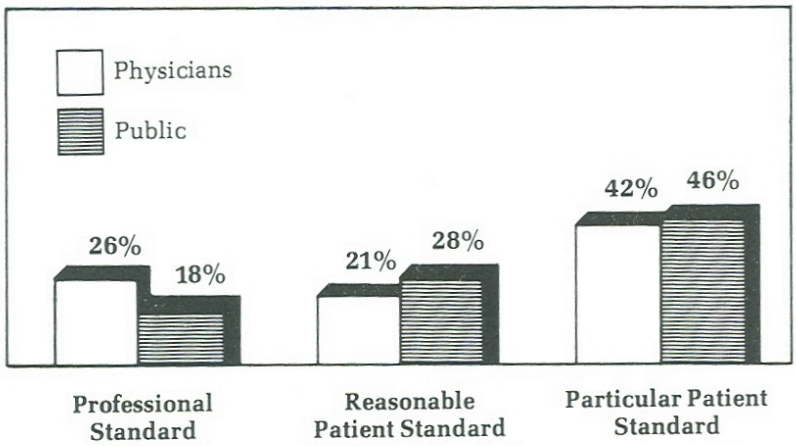
Finally, both groups were asked which disclosure standard was best (see Figure 4). More than 40% of the physicians and the public thought that a standard based on the informational needs of a particular patient was preferable to a reasonable patient or physician standard.

Physicians were then asked whether they knew which standard applied in the state(s) in which they practiced. Only 23% said they did. Surgeons were more likely than any other specialty to say they knew (30%), and older doctors were more likely than younger ones to claim knowledge of their state's standard (27% versus 17%). Overall, of the 23% who claimed to know the standard, 54% of those practicing in states that have a standard gave the correct answer.

The Use of Consent Forms. Consent forms, which were originally intended as documentation of disclosure and con-

Figure 4: The Best Disclosure Standard: Public and Physician Views*

Source: Commission survey conducted by Louis Harris and Associates, 1982



*1 % of the public and 8 % of physicians thought there should be no standard; 7 % of the public and 4 % of physicians were not sure what standard they preferred.

sent, have in many cases come to substitute for the very processes they are intended to substantiate.[68] Furthermore, there appears to be substantial variation among health care professionals about when consent forms are required[69] deriving in many cases from institutional differences in interpretation of the law. And the law is, in fact, often unclear and nonspecific about the requirements for consent.

Several different consent forms are in use. Hospitals often require patients upon admission to sign a blanket consent that purports to give physicians authority to "treat as necessary." The Joint Commission on Accreditation of Hospitals requires, that separate consent forms be signed for any procedure or treatment "for which it is appropriate" and that these forms be included in the medical record.[70] It appears from one of the observational studies conducted for the President's Commission that physicians deem "procedures"—in contrast to "routine care"—as appropriate for written consent. Procedures are

68 *See, e.g.,* Bradford H. Gray, *Complexities of Informed Consent,* 437 ANN. AMER. ACAD. POLIT. SOC. SCI. 37 (1978).

69 "As a legal matter, consent forms are rarely required. Those state informed consent statutes that deal with consent forms make them permissible, not mandatory. Even the federal regulations governing the conduct of federally funded research do not require consent forms in all instances." Alan Meisel, *More on Making Consent Forms Readable,* 4(1) IRB 9 (Jan. 1982).

70 Joint Commission on Accreditation of Hospitals, ACCREDITATION MANUAL FOR HOSPITALS, Chicago, Ill. (1981) at 84-86.

done relatively infrequently and include most invasive measures, as well as major diagnostic tests that carry some risk. Risk itself, however, does not distinguish the procedures for which written consent is thought to be required; written consent is typically not obtained for medications, even when major and frequent risks attend their use.[71]

Preprinted "fill-in-the-blank" forms are used for many procedures, especially surgery. The emphasis in these forms is on obtaining permission rather than on giving information, for they state that the general categories of legally material information have previously been "fully explained." Some forms are specially prepared, as in the case of the stress tests for cardiac patients observed in one of the Commission's studies. Here the nature of the test and its attendant risks were substantially different than for invasive procedures, and the form provided the only information patients received unless they chose to initiate a discussion after reading it.[72]

In the Commission's survey, physicians were asked whether they usually obtained consent—and if so, in what form—for a variety of procedures. The frequency with which consent was obtained varied significantly with the nature of the procedure; virtually all doctors reported getting consent for inpatient surgery, and about half those surveyed reported they did not get consent for prescriptions and blood tests (see Table 3). This finding was substantiated in the Commission's two observational studies.

States' informed consent laws (with the single exception of Texas) do not delineate consent requirements on a procedure-by-procedure basis. Nor does the law on informed consent generally distinguish between oral and written consent in judging validity; that is, written consent is not required where oral consent has been given.[73] Indeed, one state's statute and the case law in three states explicitly hold that consent need not be in writing in order to be valid.[74] However, a signed written consent form is likely to make legal proof of consent significantly easier, at least in the absence of other complicating factors. Physicians' consent practices apparently reflect this assumption.

Physicians and the public were asked whether they agreed with several statements regarding consent forms (see Figure 5).

---

71 Charles W. Lidz and Alan Meisel, *Informed Consent and the Structure of Medical Care* (1982), Appendix C, in Volume Two of this Report, at section 4.

72 *Id.*

73 Hernandez v. United States, 465 F. Supp. 1071, 1073 (D. Kan. 1979); Maercklein v. Smith, 129 Colo. 72, 266 P.2d 1095, 1099 (1954).

74 Meisel and Kabnick, *supra* note 65, at 468. *See State-by-State Analysis of Informed Consent Laws* (1982), Appendix L, in Volume Three of this Report.

Table 3:

Nature of Consent Obtained for Various Procedures*

Procedure	Written Consent	Oral Consent	Written and Oral Consent	Neither
Inpatient Surgery	81%	3%	15%	0
Minor Office Surgery	26%	58%	9%	7%
Setting Bones	39%	42%	9%	8%
General Anesthesia	83%	3%	12%	1%
Local Anesthesia	21%	57%	7%	15%
Diagnostic X-rays Involving Injections	45%	35%	8%	10%
Blood Tests	2%	52%	0	45%
Prescriptions	1%	43%	2%	54%
Radiation Therapy	63%	18%	11%	4%

* The total number on which figures in this table are based varied for each procedure in order to eliminate physicians who did not perform the particular procedure. Therefore the figures refer to the proportion of physicians performing a procedure who obtained consent.

Source: Commission survery conducted by Louis Harris and Associates.

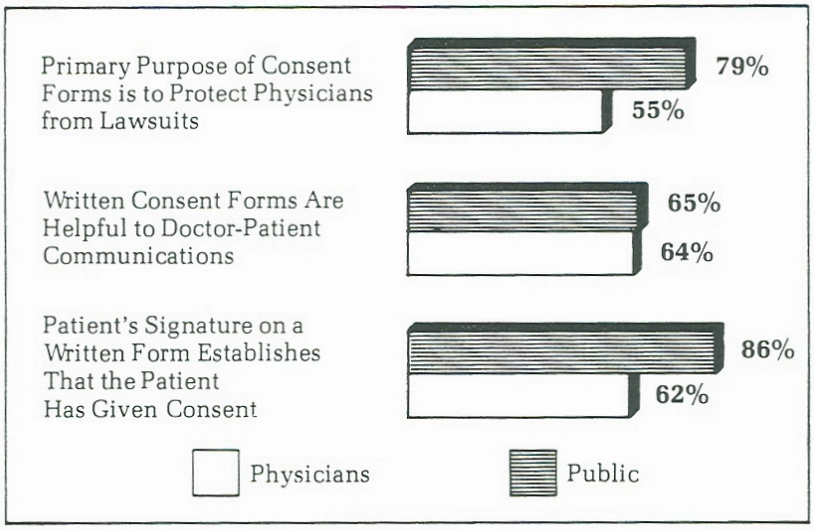
Nearly four-fifths of the public and 55% of the physicians think the primary purpose of consent forms is to protect physicians from law suits.[75] This finding seems to reflect more the advice of lawyers who represent health care professionals than the ethical basis of informed consent, in which the role of the consent form is to protect patients by ensuring that they have full information and are participating voluntarily. The majority of physicians (64%) and the public (65%) think that consent forms help doctor-patient communications. Concerning written consent forms, 62% of the physicians and 86% of the public think that a patient's signature establishes that the individual has given consent.

Of the 24 states with statutes on informed consent, only 13 make some attempt to define the legal effect of a signed consent form. As noted above, a signed form will always be some evidence that the patient actually consented to the treatment, and a jury could use it, along with other evidence, to support or rebut the existence of actual consent. However, the

75 Asking a person to sign a consent form may cause that person to refuse to sign even when he or she would be willing to give oral consent. *Cf.* Eleanor Singer, *Informed Consent: Consequences for Response Rate and Response Quality in Social Survey*, 43 AM. SOC. REV. 144, 151 (1978).

Figure 5: The Purpose and Effect of Consent Forms: Public and Physician Views

Source: Commission survey conducted by Louis Harris and Associates, 1982



type of rebuttal evidence and the circumstances under which it is allowed vary.[76]

In addition, information that must be included in the consent form in order for it to be have legal weight varies by state. In Georgia, for example, the form need not disclose any risks of the proposed procedure; only the general nature of the treatment need be set forth.[77] Louisiana, on the other hand,

76 In some states plaintiffs are allowed to prove they did not understand the standardized consent form they signed. For example, one court stated that "the effect to be given to a standard consent form is governed by the same principles used in evaluating appellant's claim under the informed consent doctrine. Thus, unless a person has been adequately apprised of the material risks and therapeutic alternatives incident to a proposed treatment, any consent given, be it oral or written, is necessarily ineffectua1." Sard v. Hardy, 379 A.2d 1014, 1019 n.3 (Md. 1977). In that case, a signed form is subject to the same type of rebuttal as would be directed against testimony that oral consent had been given. Other states restrict the type of evidence that may be presented to rebut a signed written consent form. Some allow only strict legal proof of fraud or misrepresentation. In one case, for example, the plaintiff proved that she had not read the consent form that she had signed, but since she presented no legal excuse for not reading the form, she was held to be bound by its terms. Winfrey v. Citizens & Southern Nat'l Bank, 149 Ga. App. 488, 254 S.E.2d 725, 726 (1979).

77 Winfrey v. Citizens & Southern Nat'l Bank, 149 Ga. App. 488, 254 S.E.2d 725, 726 (1979).

requires the form to list the frequency with which a specified set of risks occurs for the particular procedure involved.[78]

In the Commission's survey, 24% of the public reported that they had signed a consent form in the last year. Among those people, 71% thought their doctor explained the form satisfactorily and 29% said the explanation was unsatisfactory. Those in poor health were the most satisfied (92%) and those reporting their health status as fair were the least satisfied (60%). The explanation of such a substantial difference between these two groups (when it would seem more likely that the largest difference would be between those in excellent and those in poor health) is not clear.[79]

When the people who had signed a consent form within the last year were asked "After reading the consent form, did you feel that you fully understood the risks of the treatment you were going to undergo?," 72% said "yes," although this varied by subgroups just as the satisfaction with the explanation did. Finally, these people were asked: "Have you ever refused treatment because of what you learned about the treatment from the written consent form?" Only 5% said they had.[80]

---

78 La. Rev. Stat. Ann. § 40:1299.40(A) (West Cum. Supp. 1980).

79 Those surveyed who had no usual source of medical care, the middle-aged (35-50 years old), and those with less than a high school education were all less likely than people who had a usual source of care, the young, the old, and the better educated to view the explanation of the consent form as satisfactory.

80 Women were more likely than men to have refused treatment because of what they learned from a consent form (7% versus 3%) and those without any health insurance were the most likely (12%) to have refused treatment on this basis. Refusers were likely to be young, college-educated, in fair or poor health, and people who receive care in a doctor's office.

There is strong evidence that existing consent forms are written in extremely turgid prose and that patients have a great deal of difficulty understanding them, even if they do not admit it. A study conducted for the National Commission for the Protection of Human Subjects found that "overall, no more than 15 percent of the consent forms were in language as simple as is found, for example, in *Time* Magazine. In more than three-fourths of the consent forms, fewer than 10 percent of the technical or medical terms were explained in lay language…." U.S. Department of Health, Education and Welfare, *Protection of Human Subjects—Institutional Review Boards: Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,* 43 Fed. Reg. 56,174, 56,189 (1978). *See also* G.R. Morrow, *How Readable Are Subject Consent Forms?,* 244 J.A.M.A. 56 (1980); T.M. Grundner, *On the Readability of Surgical Consent Forms,* 302 NEW ENG. J. MED. 900 (1980).

Physicians were asked in an open-ended question what the effect of consent forms had been: 52% thought they had a positive effect (for example, that they improved patient awareness so patients knew more about their treatment and risks and asked more and better questions, encouraged more communication between doctors and patients, and provided legal protection for doctors and hospitals); 23% felt that consent forms had a negative effect (for example, that they increase patients' fears, reduced compliance, caused patients to avoid necessary treatment, made patients distrust their doctors, increased law suits, and provided no legal protection); 18% thought that informed consent forms had no effect; and 7% were not sure whether they had an effect or not.

The Commission's observational studies suggest that consent forms are typically read and signed after a decision has been made regarding treatment.[81] This is probably as it should be, assuming that the form is presented for signature after discussion and that the patient has participated in making the decision. In the Commission's view, consent forms should summarize discussion, but not be a substitute for it. Ideally, they will stimulate additional questions and discussion, as some physicians in the survey indicated, but they should not be allowed to replace such communication or to cut it off prematurely.

81 More often than not, however, discussion prior to consent form signing was nonexistent or brief. *See* Lidz and Meisel, *supra* note 71; Paul S. Appelbaum and Loren H. Roth, *Treatment Refusal in Medical Hospitals* (1982), Appendix D, in Volume Two of this Report.